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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,417	05/22/2006	Miki Kobayashi	Q94782	1747

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,417	KOBAYASHI ET AL.	
	Examiner	Art Unit	
	JENNIFER MYONG M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed December 29, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 1-3 and 8-11 under 35 U.S.C. 112, first paragraph, hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 1-3 and 8 under 35 U.S.C. 102(e) as being anticipated by Mak et al. (U.S.Patent No. 6,987,129 B2) is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 9-11 under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (U.S.Patent No. 6,987,129 B2) is being **maintained** for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed December 29, 2008 have been fully considered but they are not persuasive. Applicants argue that Mak lists combinations of many compositions varying in mechanisms, which are expected to mainly have functions to dilate smooth muscles and many diseases related to urinary tract but does not specifically describe the experimental results which show the effects of these compositions on each disease, especially on chronic pelvic pain syndrome (interstitial cystitis). This is not found to be persuasive because although Mak lists combination of many active agents varying in mechanisms, Mak specifically teaches that phosphodiesterase (PDE) IV inhibitors (i.e. roflumilast, ariflo (SB207499) also known as cilomilast) are useful for the treatment of interstitial cystitis. The specific PDE IV are clearly named and taught by Mak. Therefore, no matter how many other agents are additionally named, it does not change the relevant teaching of Mak that those two agents were known at the time the invention was made for the treatment of interstitial cystitis.

Applicants argue that Mak does not describe the experimental results which show the effects of PDE 4 inhibitors such as roflumilast and cilomilast on chronic pelvic pain syndrome. Therefore, there is no guidance in Mak, which directs or motivates one skilled in the art towards the specific combination of a PDE 4 inhibitor and chronic pelvic pain syndrome, among numerous possible combinations of compositions and diseases suggested by Mak. This is not found to be persuasive because Mak's teaching that

PDE IV including the active agents such as roflumilast, ariflo (SB207499) also known as cilomilast are effective for the treatment of interstitial cystitis, is sufficient for one of ordinary skill in the art to employ roflumilast and cilomilast for the treatment of chronic pelvic pain syndrome (interstitial cystitis) with a reasonable expectation of success.

Applicants argue that the Examiner provides no scientific or technical explanations as to why one skilled in the art would have been directed to the specific combination (use of roflumilast and cilomilast to treat chronic pelvic pain syndrome) among the numerous possibilities. This is not found to be persuasive because the specific agents were taught as having therapeutic activity because they are PDE IV inhibitors. Therefore, the scientific or technical explanations of those active agents are fully taught by Mak. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (U.S.Patent No. 6,987,129 B2).

Mak et al. teach methods for treating a variety of disorders such as **interstitial cystitis** using a variety of compounds including phosphodiesterase inhibitors. (abstract, column 4, lines 46-50, column 11, lines 37-67). Mak teaches that the

phosphodiesterase inhibitor includes roflumilast and ariflo (SB207499) which is phosphodiesterase IV inhibitors. (column 15, lines 35-45).

Mak et al. do not illustrate the actual treatment of interstitial cystitis with the phosphodiesterase IV inhibitors such as roflumilast and ariflo (SB207499).

It would have been obvious to one of ordinary skill in the art to employ phosphodiesterase IV inhibitors such as roflumilast and ariflo (SB207499) for an actual treatment of interstitial cystitis because Mak et al. teach that the instantly claimed compounds such as roflumilast and ariflo (SB207499) are disclosed by Mak et al. for the treatment of interstitial cyclists. It would have been obvious to one of ordinary skill in the art to employ any one of the agents including phosphodiesterase IV inhibitors such as roflumilast and ariflo (SB207499) when specific agents such as roflumilast and ariflo (SB207499) are taught as equally effective in the treatment of interstitial cystitis and such utility would be retained. There is a reasonable expectation of successfully treating interstitial cystitis with phosphodiesterase IV inhibitors including roflumilast and ariflo (SB207499) because Mak et al. clearly teach and suggest the employment of phosphodiesterase IV inhibitors including roflumilast and ariflo (SB207499) for the treatment of interstitial cystitis.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
March 30, 2009